REMARKS

Claims 1-16 are pending in the application.

REJECTION UNDER 35 USC 102(e)

At page 2 of the Office Action mailed September 9, 2008, the Examiner maintained the rejection of claims 1-3, 6-8 and 13-15 under 35 USC 102(e) as anticipated by Daniell (U.S. Patent 7,129,391) (the '391 patent") filed May 15, 1998) for the reasons set forth in the Office Action mailed February 19, 2008.

Applicants again traverse this rejection.

Applicants submit that the '391 patent does not enable fertile transplastomic leguminous plants, and therefore does not anticipate claims 1-3, 6-8, and 13-15. Applicants' remarks relating to this rejection in the response filed July 21, 2008, and the response filed February 9, 2009 are incorporated herein by reference.

The '391 patent discloses universal chloroplast integration and expression vectors which are stated to be competent to stably transform and integrate genes of interest into chloroplast genomes of multiple species of plants. The '391 patent states that the universal vector can be used to transform chloroplasts of widely varying species of plants without the necessity of constructing individual vectors for different plants or individual crop species, which would require first a determination of the DNA sequences of each of the chloroplast genomes. The universal chloroplast vector disclosed in the '391 patent contains tobacco chloroplast DNA flanking sequences for homologous recombination to transform other plant species. The flanking sequences are selected from transcriptionally active regions of the chloroplast genome that are highly conserved in a broad range of chloroplast genomes of higher plants, preferably from an intergenic region, referred to as a spacer region. The '391 patent states that a preferred intergenic spacer region is the spacer region between the t-RNA^{Ile} and t-RNA^{Ala} region. (Col. 5, lines 22-42)

The universal vector was used to transform soybeans and peanuts, but there is no disclosure in the '391 patent of developed and fertile transplastomic soybean or peanut plants.

Example 6 of the '391 patent briefly describes general steps of a plastidial transformation of soybean leaves with a universal chloroplast transformation that contains tobacco chloroplast flanking sequences. Figure 15 shows that some soybean embryonic shoots are resistant to the antibiotic used for selection. There is no disclosure of developed and fertile soybean plants. Similarly, Example 5 of the '391 patent, directed to peanut chloroplast transformation, also only briefly describes general steps of a plastidial transformation with the same universal chloroplast transformation vector. Figure 14 shows that some peanut embryonic shoots are resistant to the antibiotic used for selection.

Although the '391 patent states that the universal vector can be used to stably transform and integrate genes of interest into chloroplast genomes of multiple species of plants, the vectors have not been found to be an efficient means for transforming species phylogenetically distant from tobacco, as discussed in Verma and Daniell, "Chloroplast Vector Systems for Biotechnology Applications," Plant Physiology, vol. 145, pages 1129-1143, 2007, a copy of which is submitted herewith in the accompanying Information Disclosure Statement. At pages 1130-1131 in the section entitled "Universal Vector Versus Species Specific Chloroplast Vectors" the authors summarized the performance of the universal vectors. Vectors designed for transformation of the tobacco plastid genome were successfully used for potato and tomato plastid transformation, but the efficiency of transformation was significantly lower than tobacco. Only one potato and tomato chloroplast transgenic line was obtained per 35 and 87 bombarded plates, respectively, compared to about fifteen tobacco chloroplast transgenic lines often generated from one bombarded plate of tobacco. Similar lower efficiency rates were observed when petunia flanking sequences (approximately 98% homologous) were used to transform the tobacco chloroplast genome. Comparison of intergenic spacer regions among members of the Solanaceae revealed that only four regions are identical. Comparison of intergenic spacer regions of nine grass chloroplast genomes revealed that not even a single spacer region is identical among all sequenced chloroplast genomes. Verma and Daniell concluded that the concept of a universal vector is applicable when a higher level of homology exists among plant species but will be less efficient than species-specific chloroplast vectors.

Even in the Solanaceae family, to which tobacco, potato, and tomato belong, a significant decreased efficiency is observed in chloroplast transformation when the universal vector is used in potato and tomato. Based on these observations, transformation efficiency of soybeans and other leguminous plants would similarly be significantly decreased because they belong to a different plant family, Fabaceae, and are even further removed phylogenetically from tobacco than potato and tomato. Dufourmantel et al. noted in the paragraph bridging pages 482 and 483, that soybean plastid DNA sequences available in databases show an organization different from the tobacco plastome but similar to that of Lotus japonicus, another leguminous plant. The authors noted that the *rbcL* and *accD* genes, adjacent in the tobacco plastome exhibit different locations in the soybean plastid DNA. The authors also found that the publicly available sequences for soybean did not correspond to the sequences they obtained after their own sequencing when developing their transformation vector.

The statements of Dr. Daniell in the Verma and Daniell publication regarding the significant decrease in transformation efficiency of the universal vector when used in species other than tobacco, when viewed in conjunction with the disclosures of the '391 patent and the other art of record, clearly imply that '391 patent does not disclose fertile transplastomic leguminous plants.

Applicants again respectfully submit that the '391 patent does not anticipate claims 1-3, 6-8 and 13-15. For at least the reasons discussed above and in Applicants' responses of record, the '391 patent does not provide an enabling disclosure of fertile transplastomic plants, and thus does not anticipate the claims of the present application. Withdrawal of this section 102(e) rejection is again respectfully requested.

REJECTION UNDER 35 USC 103

At pages 4-7 of the Office Action mailed September 9, 2008, the Examiner maintained the rejection of claims 1-16 under 35 USC 103 as obvious over Maliga et al. (U.S. Patent 5,877,402; the '402 patent) in view of von Allmen (GenBank Accession No. X7675) for the reasons set forth in the Office Action mailed February 19, 2008. In the Advisory Action, the

Examiner stated that the Applicants have not shown why it would not be obvious to replace the tobacco flanking regions with the corresponding one from soybean plants.

Applicants again traverse this rejection. Applicants' remarks relating to this rejection in the response filed July 21, 2008, and the response filed February 9, 2009 are incorporated herein by reference.

As discussed in Applicants' responses to the previous Office Actions, it was well-recognized in the art that application of transplastomic technology to plants other than tobacco was hindered by limitations in transformation protocols and tissue culture systems. Maliga and his co-inventors recognized that, at the time of filing of their patent, it was not possible for persons skilled in the art to produce fertile transplastomic plants, except possibly for a small number of species, using the teachings therein because the technology to culture and regenerate most species of plants was simply unknown.

In the Advisory Action, the Examiner stated that the Applicants have not shown why it would not be obvious to replace the tobacco flanking regions with the corresponding one from soybean plants. As discussed in Applicants' previous response, even if, assuming for the sake of argument, a person skilled in the art were motivated to combine the teachings of Maliga et al. and von Allmen, he would not have been able to regenerate fertile transplastomic plants, because methods for regenerating fertile transplastomic plants were unknown, due to a number of art-recognized obstacles relating to plastid transformation technology and regeneration protocols, which prevented the production of the plants. Persons skilled in the art therefore had no reasonable expectation of producing fertile transplastomic leguminous plants, even if, for the sake of argument, they might have been motivated to attempt to produce them.

Applicants were the first to obtain fertile transplastomic leguminous plants. Prior to the present application, there were no reports of fertile transplastomic leguminous plants, despite attempts by Zhang et al. and attempts by Daniell in the '391 patent, which Dr. Daniell implicitly admitted were non-enabling in his later publication Daniell et al. (2005). In view of the failure of others skilled in the art to produce fertile transplastomic plants, and the art-recognized obstacles to producing fertile transplastomic plants, except for tobacco, there was no reasonable expectation that fertile transplastomic leguminous plants could be obtained.

Claims 1-16 are not obvious in view of the '402 patent and von Allmen. Withdrawal of this section 103 rejection is again respectfully requested.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is respectfully requested and an early Notice of Allowance is earnestly solicited.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 03-2775, under Order No. 05500-00148-US. A duplicate copy of this paper is enclosed.

Dated: April 6, 2009

Respectfully submitted,

Electronic signature: /Liza D. Hohenschutz/
Liza D. Hohenschutz
Registration No.: 33,712
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
P. O. Box 2207
Wilmington, Delaware 19899-2207
(302) 658-9141
(302) 658-5614 (Fax)
Attorney for Applicant